

PTO/SB/17 (12-04v2)
Approved for use through 07/31/2006. OMB 0651-0032
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Under the Paperwork Reduction			o respond to	a collection of info			
Fees pursuant to the Consolidate	on 12/08/2 ed Approprie		), <del>                                    </del>			e if Knowr	).
FEE TRA	NS	MITTAL	Applic	ation Number	10/666,		
			<u>~</u>		09/19/20		1.2
For	FY 2	UUO		lamed Inventor	HARTLE	Y, Amand	a April
Applicant claims small er	ntity status	See 37 CFR 1.27		ner Name	PEFFLE	Y, Michael	
			Art Ur	ilt	3739		
TOTAL AMOUNT OF PAYMI	ENT (\$)	230	Attorn	ey Docket No.	12361-1	5US	
METHOD OF PAYMENT	check all	that apply)					
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2. EXCESS CLAIM FEES		100	U'-	0	v	0	mall Entity
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3. APPLICATION SIZE FE If the specification and dr	E	'. 'v T	ooner (ev	luding électro	nically fil	ed seguenc	a or computer
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gnature	VI		Registra (Attorney)	ion No. Agent) 34963		Telephone	416.216.3903
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**PATENT** 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Baylis Medical Company Inc.

Attorney Docket: 12361-15US

Serial No.: 10/666,301

Group Art Unit: 3739

Filed: September 19, 2003

Examiner: Michael Peffley

For:

SURGICAL PERFORATION DEVICE WITH CURVE

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 CFR 1.56, Applicant hereby submits a Supplemental Information Disclosure Statement on Form PTO/SB/08A and SB/08B (2 sheets). Copies of the non-U.S. patent references and non-patent references are enclosed.

Applicant reserves the right to contest the applicability of the enclosed as prior art against the subject application.

This Supplemental Information Disclosure Statement is being filed subsequent to the issuance of a first office action, and therefore fees of official \$180 are submitted herewith on the attached fee transmittal sheet. However, the Commissioner is authorized to charge any deficiencies or overpayment to Deposit Account No. 195113.

Respectfully submitted,

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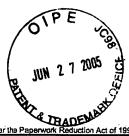
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Date: June 27, 2005



Substitute for form 1449/PTO

Sheet 1

PTO/SB/08A (08-03)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 3

Complete if Known Application Number 10/666,301 Filing Date 09/19/2003 First Named Inventor **Amanda April HARTLEY** Art Unit 3739 Examiner Name Michael Peffley Attorney Docket Number 12361-15US

		<u> </u>	U. S. PATEN	T DOCUMENTS	
Examiner Initials*	Cite: No.1	Document Number  Number-Kind Code <sup>2 (# Impired)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cled Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		<sup>US-</sup> 5,683,366	11-04-1997	Eggers et al.	· .
		<sup>US-</sup> 5,904,679	05-18-1999	Clayman	
		<sup>US-</sup> 6,814,733	11-09-2004	Schwartz et al.	
		<sup>US-</sup> -5,364,393	11-15-1994	Auth et al.	
		<sup>US-</sup> 5,098,431	03-24-1992	Rydell	
		<sup>US-</sup> 4,682,596	07-28-1987	Bales et al.	
		<sup>US-</sup> 6,293,945	09-25-2001	Parins et al.	
		<sup>US-</sup> 4,936,281	06-26-1990	Stasz	
·		<sup>US-</sup> 4,928,693	05-29-1990	Goodin et al.	
		<sup>US-</sup> 6,296,615	10-02-2001	Brockway et al.	
		<sup>US-</sup> 5,403,338	04-04-1995	Milo	
		<sup>US-</sup> 6,650,923	11-18-2003	Lesh et al.	
		<sup>US-</sup> 5,921,957	07-13-1999	Killion et al.	
		<sup>US-</sup> 3,448,739	06-10-1969	Stark et al.	
		us- 5,281,216	01-25-1994	Klicek	
		<sup>US-</sup> 6,811,544	11-02-2004	Schaer	
		<sup>US-</sup> 2002/0123749	09-05-2002	Jain	
		<sup>US-</sup> 2002/0169377	11-14-2002	Khairkhahan et al.	
		US-			

	FORE	IGN PATENT DOCL	INENTS		_
Cite No.	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
	Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>3</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T
	EP-0315730	05-15-1989	Osypka		
	WO-9320747	10-28-1993	Rosar		
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Examiner Signature	:		Date Conside	ered	

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Translation is stached.

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	ute for form 1449/PTO			Complete if Known			
	•			Application Number	10/666,301		
		4.7	CLOSURE	Filing Date	09/19/2003		
STA	STATEMENT BY APPLICANT			First Named Inventor	Amanda April HARTLEY		
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(out to many shades as necessary)			( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( (	Examiner Name	Michael Peffley		
Sheet	2	of	3	Attorney Docket Number	12361-15US		

Evanines	0:4-	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
=	1	CA PEDRA, LN DE SOUSA, SR PEDRA, WP FERREIRA, SL BRAGA, CA ESTEVES, MV SANTANT, JE SOUSA, VF FONTES: "New Percutaneous techniques for perforating the pulmonary valve in pulmonary atresia with intact ventricular septum". Arq Bras Carlol. 77(5):471-48 (2001).	
	2	DG NYKANEN, J PHIKALA, GP TAYLOR, LN BENSON. "Radiofrequency assisted perforation of the atrial septum in a swine model: feasibility, biophysical and histological characteristics". Circulation. 100(Suppl 1):I-804 (1999).	
	3	Baylis Medical Company Inc. "Radio Frequency Perforation System". (2001).	
	4	"ABSTRACT of European Patent No. 0315730 to Osypka". (1989).	
	5	Boston Scientific Corporation. "http://www.bostonscientific.com/med_specialty/deviceDetail.jsp?task=tskBasicDevice.jsp&sectionId=4&relId=1, 20,21,22&deviceId=488&uniqueId=MPDB58". Explorer ST Cahteters. 2 pages. (Date or printing - June, 2005)	
	6	Boston Scientific Corporation. "http://www.bostonscientific.com/med_specialty/deviceDetail.jsp?task=tskBasicDevice.jsp&sectionId=4&relld=2,74,75,76 &deviceId=556&uniqueId=MPDB4320". Impulse Angiographic Catheter. 2 pages. (Date of printing - June, 2005)	
	Ż	Boston Scientific Corporation. "http://www.bostonscientific.com/med_specialty/deviceDetail.jsp?task=tskBasicDevice.jsp&sectionId=4&relId=2, 74,75,76&deviceId=11026&uniqueId=MPDB2799". PT2 Guide Wire. 2 pages. (Date of printing - June, 2005)	
	8	IntraLuminal Therapeutics, Inc. "http://www.intraluminal.com/products/catheter.html". Safe Cross Support Catheter. 1 page. (Date of printing - June, 2005)	
	9	Lake Region Manufacturing, Inc. "http://www.lakergn.com/jinc.htm". Paragon Güidewire. 2 pages. (Date of printing - June, 2005)	
	10	Medtronic Inc. "http://www.medtronic.com/epsystems/diagnostic_catheters.html". Diagnostic Catheters. 7 pages. (Date of printing - April, 2005)	

Examiner	Date	
Signature	Considered	

<sup>&</sup>quot;EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to epplicant.

1 Apolicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The Information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

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Substitute for form 1449/PTO	Complete if Known			
	Application Number	10/666,301		
INFORMATION DISCLOSURE	Filing Date	09/19/2003		
STATEMENT BY APPLICANT	First Named Inventor	Amanda April HARTLEY		
(Use as many sheets as necessary)	Art Unit	3739		
(See as many sheets as necessary)	Examiner Name	Michael Peffley		
Sheet 3 of 3	Attorney Docket Number	12361-15US		

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
Initials*	No.1	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	11	Johnson & Johnson Geteway, LLC.  Tittp://www.injgateway.com/home.jhtml?loc=USENG&page=viewContent&contentId=fc0de00100001435&nodekey=/Prod_Info/ Specialty/Arrhythmia_Management/Electrophysiology/EP_Diagnostic_Catheters*. EP Diagnostic Catheters. 2 pages. (Date of printing - June, 2005)	
	12	Johnson & Johnson Gateway, LLC. http://www.inigateway.com/home.jhtml;jsessionid=JNSFriTWOAOICOCQPCCECPJYKB2IIWNSC7icc=USENG&page=viewContent&contentUd=fcOde00100000524&nodekey=/Prod_Info/Specialty/Cardiovascular_and_Thoracic/Cardiac_Diagnosis_Interve_ntions/Diagnositic_Wires&_requestid=228805*. Diagnositic Guidewires. 4 pages, (Date of printing - June, 2005)	
	13	H JUSTINO. LN BENSON, DG NYKANEN. "Transcatheter Creation of an Atrial Septal Defect Using Radiofrequency Perforation". Catheter Cardiovasc Interv. 54(1):83-87 (September: 2001).	
	14	N.SHIMKO, P.SAVARD, K.SHAH. "Radio frequency perforation of cardiac tissue: modelling and experimental results". Med. Biol. Eng. Comput. 38:575-582 (2000).	
	15	T ABDEL-MASSIH, Y BOUDJEMLINE, P BONHOEFFER. "Unusual interventional management in an adult with tetralogy of Fallot". Cardiol Young. 13(2):203-205 (April, 2003).	
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:	17	CA PEDRA, RM FILHO, RS ARRIETA, R TELLEZ, VF FONTES. "Recanalization of a discrete atretic right pulmonary artery segment with a new radiofrequency system". Catheter Cardiovasc Interv. 60(1):82-87 (September, 2003)	
-	18	HW KORT, DT BALZER. *Radiofrequency perforation in the treatment of acquired left pulmonary atresia following repair of tetraligy of Fallot*. Catheter Cardiovasc Interv. 60(1):79-81 (September, 2003)	
	19	G VELDTMAN, A PEIRONE, LN BENSON. "Radiofrequency perforation of the atrial septum: Preliminary experimental evaluation and development." PICS VII Abstracts. Catheter Cardiovasc Interv. 60(1):132 (September, 2003)	
	20	F GODART, C FRANCART, GM BREVIERE, C REY. "Pulmonary vavulotomy with the Nykanen radiofrequency guide in pulmonary stresia with intact interventricular septum". Arch Mai Coeur Vaiss. 96(5):517-520 (May, 2003). 'Article is in French with an English summary.	

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Examiner			Date	
Signature		:	Considered	

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